Overview of the VCU Human Research Protection Program’s Portfolio

### Quick Statistics about VCU’s Portfolio of Human Subjects Research

<table>
<thead>
<tr>
<th>VCU IRB</th>
<th>External IRB’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Active IRB Studies (incl. exempt)</td>
<td>2,054</td>
</tr>
<tr>
<td>Active Exempt Studies</td>
<td>1,251</td>
</tr>
</tbody>
</table>

% of All Active Studies with Sponsored Project or Non-Profit Funding: 25% for VCU IRB, 60% for External IRB’s

Within VCU’s total portfolio of 2,531 studies, there are:
- 867 Principal Investigators
- 646 Student-Initiated Studies
- 685 Clinical Research Studies (27%)
- 597 Clinical Trials (24%)
- 463 FDA-regulated Studies (18%)
- 92 COVID-19 Studies
- 17 Expanded Access Protocols

### ACTIVE VCU IRB STUDIES BY RESEARCH TYPE (INCLUDING EXEMPT STUDIES)

- **Biomedical research topics**: 1,382 studies (55%)
- **Social-behavioral research topics**: 1,144 studies (45%)

### VCU IRB Initial Submissions Approved during Fiscal Year 2019-2020

- University College: 1
- The Arts: 3
- Administrative Units: 6
- Engineering: 7
- Business: 12
- Social Work: 12
- Massey Cancer Center: 14
- Wilder School of Government and Public Affairs: 14
- Health Professions: 15
- Nursing: 19
- Dentistry: 25
- Pharmacy: 49
- Education: 54
- Humanities and Sciences: 91
- Medicine: 321

Data as of 8/5/2020

Questions or concerns about these metrics? Contact Elicia Preslan (ORSP@vcu.edu)
FY2019-2020 Time Metrics for All Approved Initial Submissions:

Overall, initial submissions (exempt, expedited and full board) spent a median of 42 calendar days with the IRB.

<table>
<thead>
<tr>
<th>Overall Median Number of Calendar Days from Submission to Approval FY 2019-2020</th>
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<tbody>
<tr>
<td>IRB Time only</td>
</tr>
<tr>
<td>IRB + PI Time</td>
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</tbody>
</table>

Time to approval has been steadily decreasing for exempt and expedited submissions since January 2020 when the IRB instituted several operational changes and hired additional staff.

In the graph below, the full board times to approval are greatly impacted by the small number of submissions. Time to approval was at a low point in Jan-March 2020 because the only new studies being submitted were COVID-19 trials, and the IRB worked to review them all very quickly.

![Median Calendar Days to Approval for Initial Submissions (IRB Time Only)](image)

<table>
<thead>
<tr>
<th>NUMBER OF INITIAL SUBMISSIONS APPROVED EACH QUARTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
</tr>
<tr>
<td>Jul-Sep 2019</td>
</tr>
<tr>
<td>Oct-Dec 2019</td>
</tr>
<tr>
<td>Jan-Mar 2020</td>
</tr>
<tr>
<td>Apr-Jun 2020</td>
</tr>
</tbody>
</table>

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FY2019-2020 Submission Volume Statistics:

The VCU IRB receives and processes about 3,000 submissions per year and 450 submissions per month. This includes all types of submissions: new studies, amendments, continuations, closures, and reports.

**Graphs:**

- **Total Submission Volumes:**
  - NCI Central IRB, 26.1%
  - Other IRB, 88.3%
  - Western IRB, 64.2%
  - IRB Panel A, 3081, 94%

- **Monthly VCU IRB Submission Volumes - January to July 2020**

- **Monthly External IRB Submission Volumes - January to July 2020**

About half of what the IRB’s processes in any given month is re-submitted changes.
FY2019-2020 Approval Volume Statistics:

The 2018 Common Rule is the federal regulations that govern human subjects research. It went into effect in January 2019, and among the major changes were: expanding the categories of exemption, changing the requirements for continuing reviews for expedited studies.

The impact of the 2018 Common Rule can be seen in the below. Studies that used to require expedited review are now qualifying for exemption. Also, approximately one-third of the expedited volume was made up of continuing reviews, which no longer need to be submitted (studies submit annual status updates instead).

The number of full board approvals went up in the past year because many studies needed to submit amendments for COVID-19 changes.

![TOTAL APPROVAL VOLUME (ALL SUBMISSION TYPES)](chart)

Perceptions of the IRB's customer service and review quality from the May 2019 IRB Satisfaction Survey (n=149)

<table>
<thead>
<tr>
<th>Statement</th>
<th>Rating</th>
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<tbody>
<tr>
<td>IRB staff members are a helpful resource</td>
<td>★★★★★</td>
</tr>
<tr>
<td>The IRB conducts a thorough review</td>
<td>★★★★★</td>
</tr>
<tr>
<td>The IRB is a partner in research</td>
<td>★★★★½</td>
</tr>
<tr>
<td>The changes requested by IRB reviewers are reasonable</td>
<td>★★★★½</td>
</tr>
<tr>
<td>The IRB's reviews are generally consistent</td>
<td>★★★★</td>
</tr>
</tbody>
</table>